K122507

CardinalHealth

SEP 26 2012

1430 Waukegan Road
McGraw Park, IL 60085

www.cardinal.com

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
DuraBlue™ Sterilization Wrap

Manufacturer:	Cardinal Health 200, LLC 1430 Waukegan Road McGaw Park, IL 60085
Regulatory Affairs Contact:	Lavenia Ford 1430 Waukegan Road McGaw Park, IL 60085
Telephone Number:	(847) 887-3323
Date summary Prepared:	August 09, 2012
Trade Name:	DuraBlue™ Sterilization Wrap
Classification:	Class II per 21 CFR § 880.6850
Classification Name:	Sterilization Wrap
Predicate Device:	K112283 - DuraBlue™ Sterilization Wrap – STERRAD 100S K120658 - DuraBlue™ Sterilization Wrap – STERRAD 100S

Description:

Cardinal Health DuraBlue™ Sterilization Wraps are double layer sterilization wraps made from 100% polypropylene spunbond-meltblown-spunbond (SMS) fabric. They are intended to be used to enclose another medical device that is to be sterilized by a health care provider by Standard and Advanced cycles of the STERRAD® NX hydrogen peroxide gas plasma sterilization system. This wrap design allows for use of the simultaneous double-wrapping technique and also allows for a sterilized pack to be opened aseptically.

This submission covers six different models of Cardinal Health DuraBlue™ Sterilization Wrap. Each model is made from material of a different basis weight, though all models utilize the same material technology.

Extensive performance testing has been completed on Cardinal Health DuraBlue™ Sterilization Wrap. Successful completion of the sterilization performance tests demonstrated that the wrap both allows for sterilization of the enclosed contents and also maintains sterility of the enclosed devices until opened within the period of time for which performance data demonstrating maintenance of sterility has been provided.

Indications for Use:

Cardinal Health DuraBlue™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider by the following modality:

- Standard and Advanced cycles of the STERRAD® NX Sterilization System.

The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s). Maintenance of package sterility was validated with real-time testing for the following durations:

- 30 days following sterilization by STERRAD® NX (Standard and Advanced cycles)

All models of DuraBlue™ Sterilization Wrap have been validated for use with the following STERRAD® NX Sterilization Cycles.

Table 1 – Validated STERRAD® NX Sterilization Cycles

STERRAD® System and Cycle	**Maximum Recommended Chamber Load**	**Intended Load**
STERRAD® NX Standard Cycle	10.7 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens • an inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens
STERRAD® NX Advanced Cycle	10.7 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens OR One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter

Table 2 - Wrap Model Recommendations[1]

Sterilization Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content Weight[2]
CH100	Very light weight package (for example: batteries)	10.7 lbs
CH200	Light weight package (for example: telescope with light cord)	10.7 lbs
CH300	Light to moderate weight package (for example: general use medical instruments)	10.7 lbs
CH400	Moderate to heavy weight package (for example: general use medical instruments)	10.7 lbs
CH500	Heavy weight package (for example: general use medical instruments)	10.7 lbs
CH600	Very heavy weight package (for example: general use medical instruments)	10.7 lbs

The following loads were used in the Sterility Maintenance Validation Study:

- **CH100:** 23 in. x 11 in. x 4 in. tray containing metal instruments
- **CH200:** 23 in. x 11 in. x 4 in. tray containing metal instruments
- **CH300:** 23 in. x 11 in. x 4 in. tray containing metal instruments
- **CH400:** 23 in. x 11 in. x 4 in. tray containing metal instruments
- **CH500:** 23 in. x 11 in. x 4 in. tray containing metal instruments
- **CH600:** 23 in. x 11 in. x 4 in. tray containing metal instruments

Note: The loads used in the Sterility Maintenance Validation Study corresponded to the maximum wrapped package content weights in Table 2.

[1]Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight and size of individual content types that were validated for the DuraBlue™ Sterilization Wraps.

Substantial Equivalence

The proposed DuraBlue™ Sterilization Wrap is substantially equivalent to the predicate devices. Both devices:

- Have the same intended use
- Have the same material composition
- Have the same physical and chemical properties
- Have the same configurations/dimensions
- Demonstrate maintenance of package sterility within the period of time for which performance data demonstrating maintenance of sterility has been provided
- Performance and safety attributes are substantially equivalent to the predicate. The physical properties of all wrap models have been characterized both before and after exposure to STERRAD® NX sterilization. The resulting data supports the conclusion that Cardinal Health DuraBlue™ Sterilization Wrap sterilized with the STERRAD® NX Standard or Advanced cycles is substantially equivalent to Cardinal Health DuraBlue™ Sterilization Wrap sterilized with the STERRAD® 100S system. The data demonstrates that the DuraBlue™ Sterilization Wrap is compatible with the Standard and Advanced cycles of the STERRAD® NX Sterilization System.

Summary of Testing

DuraBlue™ Sterilization Wrap performance has been tested in accordance with the applicable requirements recommended in the FDA's Guidance Document Premarket Notification 510(k) Submissions for Medical Sterilization Packaging System in Health Care Facilities; Draft Guidance for Industry and FDA (March 7, 2002). Testing included sterilization efficacy, event related maintenance of package sterility, physical properties, and biocompatibility in compliance with the methods of ISO 10993. Data from testing demonstrates that the performance of the DuraBlue™ Sterilization Wrap intended for use with the STERRAD® NX Sterilization System is substantially equivalent to the DuraBlue™ Sterilization Wrap intended for use with the STERRAD® 100S Sterilization System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 26 2012

Cardinal Health 200, Limited Liability Company
C/O Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K122507
Trade/Device Name: Cardinal Health DuraBlue™ Sterilization Wrap
Sterrad® NX Sterilization System, Standard and Advanced Cycles
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: September 11, 2012
Received: September 12, 2012

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardinalHealth

Indications for Use

510(k) Number (if known): K122507_____

Device Name: Cardinal Health DuraBlue™ Sterilization Wrap

STERRAD® NX Sterilization System, Standard and Advanced Cycles

Indications for Use:

Cardinal Health DuraBlue™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider by the following modality:

- Standard and Advanced cycles of the STERRAD® NX Sterilization System

The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s). Maintenance of package sterility was validated with real-time testing for the following durations:

- 30 days following sterilization by STERRAD® NX (Standard and Advanced cycles)

All models of DuraBlue™ Sterilization Wrap have been validated for use with the following STERRAD® NX Sterilization Cycles.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Devices Evaluation (ODE)

Elizabeth F. Claverie - W

Division Sign-Off
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) K122507

Table 1 – Validated STERRAD® NX Sterilization Cycles

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STERRAD® NX Advanced Cycle	10.7 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens OR One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter

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